REMARKS

After amendment, claims 1-3 remain pending in the present application, claims 4-12 having been cancelled previously without prejudice pursuant to the Examiner's restriction requirement and Applicants' election to prosecute the group I invention and a carbomer species having an allyl ether linking moiety which is hydrolytically susceptible. The present invention relates to polyanionic polymers which are linked through hydrolytically susceptible groups to afford polyanionic polymer segments of relatively small molecular weight which degrade into water soluble polymer chains which may be passed out of the body because of their limited size, which is an important aspect of the present invention. The polymers according to the present invention are susceptible to hydrolysis and used in conformity with those physicochemical characteristics. The polymers of the present invention are clearly distinguishable over the polymers of Ackerman. Support for the amendment to the claims can be found in the specification *inter alia* at page 2, first full paragraph, and in particular at lines 3-6 and the bottom of page 27 (lines 30-34) and the top of page 28. No new matter has been added by the present amendment.

The Examiner has maintained his rejection that previously filed claims 1-3 are invalid over the teachings of Ackerman under 35 U.S.C.§102 and/or 103 for the reasons which are set forth in the office action on pages 2-5 of the office action. Applicants respectfully traverse the Examiner's rejections of the instant application.

The Rejection of Claims 1-3 Under 35 U.S.C. §102 and/or 103

The Examiner has rejected previously presented claims 1-3 under 35 U.S.C. §102 as being anticipated by or in the alternative, under 35 U.S.C. §103(a) as being obvious over U.S. patent no. 2,923,692 to Ackerman ("Ackerman") for the reasons which are stated in the office action on pages 2-5. Applicants respectfully traverse the Examiner's rejection.

The present invention as set forth in claims 1-3 is directed to pre-formed hydrolytically susceptible polyanionic polymer comprising at least one hydrolytically susceptible linking moiety and at least two polyanionic polymer segments linked to the linking moiety wherein all of the polyanionic polymer segments in the polymer are linked to the whole by the linking moiety and at least 90% of the polyanionic polymer segments in the composition have molecular weights of 50 kilodaltons or less (claim 1), 40 kilodaltons or less (claim 2) or an average molecular weight which ranges from 20 kilodaltons to 40 kilodaltons and the polymeric compositions degrades (hydrolyzes) to soluble polymer chains. The pre-formed hydrolytically susceptible polyanionic polymers are particularly useful as barriers for use in treating or preventing the formation of surgical adhesions, wherein the molecular weight of the polymer segments is an important feature to allow favorable chacteristics including bioressorption (the ability of the body to excrete the polymer based upon its relatively small molecular weight and size and its relative solubility, an important feature). The present polymers have the claimed physicochemical characteristics, i.e., hydrolytically susceptible linking moieties and polyanionic polymeric segments which have a substantially low molecular weight consistent with its biological activity- to allow the polymers to degrade into polymeric segments which are soluble and which may be resorbed in vivo. Consequently, the present polymers may be used within the body to treat or prevent adhesions which occur secondary to surgery and over time, will degrade into polymeric segments or chains which are soluble and which may be resorbed, i.e., removed from inside the body. Ackerman neither discloses nor even obliquely suggests the present polymers. Indeed, if anything, the polymers of Ackerman ***teach away*** from the present invention.

Ackerman discloses ***insoluble***, but water sensitive (i.e., high swelling) mucilaginous polymers (column 3, lines 1-27) which are crosslinked polyanionic polymers. The polymers of Ackerman are *insoluble, but swellable* in water because of the existence of a large number of carboxy moieties in the polymer. Indeed, Ackerman emphasizes that the crosslinking agents should be *resistant* to hydrolysis (column 5, lines 20-29). Most of the polymers in Ackerman are

directed to water-stable mucilaginous polymers, not hydrolytically susceptible polymers according to the present invention. Nowhere does Ackerman suggest that the polymers may be used to treat or prevent surgical adhesions or that the molecular weight of the water soluble polyanionic polymer segments is important to the functioning of the polymer as it is in the present invention. In the case of the Examiner's rejection and in particular the disclosure in Ackerman (Example IV, Polymers C-E and J), there is no discussion whatsoever about the importance of the molecular weight of the polyanionic segments or the required water solubility of the polymer chains which are produced upon degradation (hydrolysis of the crosslinking agents) as in the present invention. Indeed, if anything, the polymers of Ackerman are completely distinguishable from the present invention.

In Example IV of Ackerman, there is all indication that the polymer chains (which correspond to those of the present invention) are *not* soluble in water. For example, Ackerman states at column 13, lines 3-18 (Example IV):

> The mucilages in every case are smooth and non-grainy in nature and have a uniformly higher viscosity than similar mucilages made from similar polymers prepared in water or dioxane and dried and reground. The viscosity of these mucilages are several times as high as tragacanth or sodium alginate, the 1.5% mucilages being well above 1000 poises in viscosity. The mucilages evidence good cohesion and high yield point adapting them for pharmaceutical mucilaginous applications such as toothpastes, surgical jellies, contraceptive jellies, burn remedies, and other applications where high demulcent action is desired. In addition, these polymers contain ***such low soluble content*** and so tenaciously retain water against osmotic pull that they are admirably adapted for use as bulk laxatives, ion exchange resins for use in vitro (in the gastro-intestinal tract) and as carriers, bulking agents, etc. (Emphasis added).

The above passage in Ackerman clearly discloses that Ackerman did not teach or suggest polymers according to the present invention which require for activity limited molecular weight

and water *solubility* of the polymer chains which remain after the polymer degrades or hydrolyzes. If anything, the fact is that Ackerman teaches away from the present polymers inasmuch as Ackerman requires greater viscosity and a ***low soluble content***, something which is completely contrary to the present invention. Noted also is the fact that Ackerman does not disclose the use of polymers internal to the body of a patient, precisely failing to understand the unique nature of polymeric compounds according to the present invention and their use in applications which rely on the novel and patentable features of the compositions- i.e., a polymer which degrades into water soluble polymeric chains having a limited size or molecular weight in order for the polymer to be resorbable from a surgical patient's body.

There is absolutely no disclosure in Ackerman that the polymers of Example IV have polymeric segments which meet the limitations of the present invention or the importance of molecular weight to provide polymers which are bioresorbable. Moreover, if anything, Ackerman suggests larger, non-soluble polymers, thus *teaching away* from the present invention. Ackerman cannot be taken to anticipate the present invention because there is absolutely no mention of molecular weight, the importance of molecular weight to the biological activity of the polymer or that the Ackerman polymers are susceptible to water hydrolysis such that the water soluble polyanionic segments are linked together through the hydrolytically susceptible linking moieties to form the copolymer. Indeed, if anything, Ackerman teaches to make polymers which do not have soluble polymeric segments or in which the polymer chain size is limited as in the present invention.

Indeed, the examples upon which the Examiner relies make no disclosure or attempt to control molecular weight by varying the process for producing the polymer. In contrast to the present copolymers which will hydrolyze into individual water soluble polymeric units of relatively small molecular size which is consequential to the biological activity of the present invention, the Ackerman polymers are devoid of any teaching which would lead to the presently claimed invention and in fact, suggest that the polymeric chains are much larger than the instant

polymeric chains due to their insoluble nature. There is absolutely no evidence that any of the polymers of Ackerman meet the limitations of the present claims and consequently, Applicants respectfully submit that the Ackerman polymers do not anticipate the present invention.

Certainly the teachings of Ackerman do not render the present invention obvious. There is absolutely no motivation to produce the compositions of the present invention from the teachings of Ackerman inasmuch as Ackerman is not concerned with bioresorbability of water soluble polyanionic polymeric segments of limited size linked together through hydrolytically susceptible linker moieties. There is absolutely no attempt in the Ackerman examples to control the molecular weight of the polymer consistent with its use according to the present invention, *and there is absolutely no need to.* Although Ackerman does disclose polymeric formulations which can be used in the gastrointestinal tract, etc. there is no evidence that these polymers of Ackerman are formulated to be water susceptible in a manner which will result in small water soluble polymeric polyanionic segments of limited molecular weight/size in order to be passed out of a patient's body through the kidneys, an important feature of the present invention related to its biological function. There is no need for Ackerman to control for molecular weight of the disclosed polymers and there is no indication that he did so.

There is an actual teaching and further motivation in Ackerman to provide insoluble polymers. Indeed, if anything, there is motivation in Ackerman to *increase* the molecular size of the polymers in order to avoid having the polymers be absorbed from the gastrointestinal tract. Ackerman, in this sense, represents a teaching away. This stands in marked contrast to the present invention where the water solubility, molecular weight and size of the polyanionic segments is a primary feature of the present invention because it provides the presently claimed invention with the ability to be used in a patient's body at a surgical site and be resorbable from that patient's body- a characteristic which is not even considered by Ackerman and is excluded by his use of polymeric composition in the gastrointestinal tract.

It is respectfully submitted that Ackerman neither teaches nor renders obvious the present invention. The mere fact that Ackerman discloses hydrogels neither anticipates the present invention nor renders the present invention obvious. The hydrogel characteristic will be a function of the number of carboxy moieties and the relative hydrophilicity of the polymer- it has little to do with molecular weight. If anything, the polymers of Ackerman have higher molecular weight, not lower molecular weight as discussed at column 13, lines 7-11, which disclose the polymers as having high viscosities. There is absolutely nothing disclosed in Ackerman which would motivate the routineer to produce the polymeric compositions according to the present invention because there is simply no activity or biological problem discussed or disclosed in Ackerman (resorbability of polymers from a patient) which would require a solution such that the present compositions would be produced. Indeed, as discussed above, in Ackerman there is motivation to *increase* molecular weight, not decrease molecular weight and make the polymer chains water soluble as in the present application. There is accordingly absolutely no motivation in Ackerman to produce the present invention.

The Examiner argues that the polymers of the present invention and the polymers of Ackerman are identical. That is simply not the case. The polymeric compositions of Ackerman and those of the present invention are markedly distinguishable in both composition and in use. The polymers of Ackerman and the polymers of the present invention are clearly not identical (given the distinguishable biological activity and uses of the polymers in the two cases), because Ackerman emphasizes insoluble polymers with increased viscosity, whereas the present invention requires polymers which degrade (hydrolyze) to polymeric chains of small size which are highly water soluble in order to promote resorbability from a surgical site in a patient. There is simply no way a cogent argument for an inherent anticipation can be made from Ackerman.

As the Court said in *Continental Can Co. USA, Inc. v. Monsanto Co.*, 20 USPQ2d 1746, 948 F.2d 1264 (Fed. Cir. 1991):

To serve as an anticipation when the reference is silent about the asserted inherent

characteristics, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence *must make clear* that the missing descriptive matter is *necessarily* present in the thing described in the reference and that it would be so recognized by persons of ordinary skill. [Enphasis added].

In re Oelrich, 212 USPQ 323, 326, 666 F.2d 578, 581 (CCPA 1981) (quoting *Hansrig* v. *Kemmer*, 40 USPQ 665, 667, 102 F.2d 212, 214 (CCPA 1939) provides:

> Inherency, however may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performed or the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

Here, the Examiner has not made out a cogent case that example 4 of Ackerman will produce inherent results which will meet the limitations of the claim- in fact, quite the opposite is true. A*ll evidence from Ackerman* points to example 4 *not* inherently producing the claimed invention, not even ***accidentally***, because there is simply no rationale or reason to make the present compositions, which are directed to a completely distinguishable biological problem- bioresorbable polymers. It is respectfully submitted that example 4 of Ackerman does not produce and cannot produce results which would anticipate the present invention and it is clear that there is no anticipation here. As the Court said in *In re Newell,* 13 USPQ2d 1248, 891 F2d 899 (Fed. Cir. 1989), *Cert. Denied* 493 US 814 (1989), "A retrospective view of inherency is not a substitute for some teaching or suggestion which supports the selection and use of the various elements in the particular claimed combination."

Inasmuch as there is no disclosure of the present invention in Ackerman and absolutely no motivation or suggestion to produce polymeric compositions according to the present invention, it is respectfully submitted that the present invention of amended claims 1-3 is neither

disclosed nor rendered obvious. The present invention is clearly patentable.

It is respectfully submitted that the claimed invention is in compliance with the requirements of 35 U.S.C. For the above reasons, Applicant respectfully asserts that the claims set forth in this amendment are now in condition for allowance and such action is earnestly solicited.

Applicant has neither cancelled nor added any claim. No fee is due for the presentation of this amendment. Small entity applies to the present application. If the Examiner determines that any fee is due for the presentation of this amendment, authorization to charge deposit account 04-0838 is hereby acknowledged. The Examiner is cordially requested to call the undersigned should the Examiner wish to expeditiously advance prosecution of this application.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on June 30, 2006.

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